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Ideas for Medicine, Inc.  
Pruitt Safety Occlusion Catheter  
510(k) Notification

**SAFETY and EFFECTIVENESS SUMMARY**

**PROPRIETARY NAME:**

Pruitt Safety Occlusion Catheter

**COMMON USUAL NAME:**

Vascular Catheter

**CLASSIFICATION:**

Class II

**CLASSIFICATION NUMBER:**

74.DXG

**DEVICE DESCRIPTION:**

The Pruitt Safety Occlusion Catheter is a single lumen balloon catheter. There is an external safety balloon designed to inflate when the intraluminal balloon reaches 17 psi. This reduces the possibility of balloon overinflation. All materials have been used by Ideas for Medicine, Inc. for many years to manufacture other Class II devices. All materials have been subject to Biocompatibility testing. <sup>(1)</sup> Every lot is supplied sterile and non-pyrogenic.

**SUBSTANTIAL EQUIVALENT:**

The intended use of this device is for occlusion of the internal carotid artery during endarterectomy. The Pruitt Inahara Shunt is a balloon shunt that provides a temporary bypass during carotid endarterectomy and features the external safety balloon. The Pruitt Occlusion Catheter provides vessel occlusion without shunting. The Pruitt Safety Occlusion Catheter combines the 2 devices and provides an alternative to clamping during carotid endarterectomy where the surgeon chooses not to shunt.

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<sup>1</sup> "Use of International Standard ISO-10993, Biological Evaluation of Medical Device, Part I, Evaluation and Testing" for Devices in Contact with Blood (short term duration).